JUL 1 0 2001

K011311

ELECTRONIC INDUSTRY AND TRADE CO, LTD

TURAN GUNES BUL
KONRAD AD CAD 59/1
SANCAK, CANKAYA, 06550
ANKARA, TURKEY
TEL:+90 312 491 6010
FAX:+90 312 491 6011

30 APR 2001

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD
TURAN GUNES BUL KONRAD AD CAD
59/1 SANCAK CANKAYA, 06550
ANKARA
TURKEY

TEL:+90 312 491 6010
FAX:+90 312 491 6011

CONTACT PERSON: CENGİZ KABAKCI
ASSISTANT GENERAL MANAGER

2. Device Identification

Proprieatary Device Name:	**UROlogic** Urological Table
Common/Generic Device Name:	Fluorocsopic Imaging System, Urological Table
Classification Name:	SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED
Product Code:	90 JAA
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.1650

3. *Substantial Equivalence*

The **URO***logic* Urological Table is substantially equivalent to the following currently marketed devices:

- OEC Uroview 2600 (K940295)
- Liebel-Flarsheim Hydradjust IV (K943581)

4. *Description of Device*

URO*logic* is a universal fluoroscopic x-ray diagnostic system intended for use in providing x-ray imaging of patient with an undertable image intensifier. The system consists of a floor mounted tilting patient support table, x-ray generator, x-ray tube assembly, image intensifer and the tv system. The system is operated via tableside control panel, foot/handswitches and x-ray control panel. The system comes with a tripple mode image intensifier, a CCD camera with one frame memory, x-ray tube with housing and an image monitor.

The tabletop can be moved motorized in longitudinal and lateral directions. The table can be tilted –15 to +87 degrees. Cranial movement of connected x-ray tube and image intensifer assembly gives the operator the advantage of scanning without moving patient. System has a stationary grid and casette holder for radiographic films. Patient positioning and other accessories are also provided.

5. *Intended Use*

URO*logic* is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to urologic and endoscopic procedures. The system may be used for other imaging applications at physician's discretion.

6. *Technological Characteristics*

URO*logic* Urological Table employs the same technological characteristicsas the predicate devices. This device is intended for the same applications as the currently marketed predicate devices. All systems are image intensified x-ray imaging systems with an overtable x-ray tube assembly. Like the predicate devices, **URO***logic* Urological Table consists of basic the basic patient suport table, and standard system components: x-ray generator, x-ray tube, Image Intensifier, TV system and monitor(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Cengiz Kabakci
Assistant General Manager
PCK Electronic Industry and Trade Co, Ltd.
Turan Gunes Bul Konrad AD CAD
59/1 Sancak
CANKAYA 06550
ANKARA TURKEY

MAY 16 2012

Re: K011311
Trade/Device Name: IURO) Logic (Urology x-ray table)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: April 30, 2001
Received: April 30, 2001

Dear Mr. Kabakci:

This letter corrects our substantially equivalent letter of July 10, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Applicant: PCK ELECTRONIC INDUSTRY AND TRADE CO, LTD

TURAN GUNES BUL KONRAD ADENAUER CAD
59/1 SANCAK, CANKAYA
O6550, ANKARA
TURKIYE

510(k) NUMBER: K011311

DEVICE NAME: **URO*logic*** Urological Table

INDICATIONS FOR USE:

URO*logic* is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011311